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10/593,145

09/18/2006

Yuichi Oku

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EXAMINER

LUNDGREN, JEFFREY S

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,145	Applicant(s) OKU ET AL.	
	Examiner JEFFREY S. LUNDGREN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/16/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 18, 19, 24-49, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18, 19, 24-49, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 1-14, 18, 19, 24-49, 51 and 52 are pending in the instant application and are the subject of the Office Action below.

Previous Rejection Withdrawn

Any rejection or objection to the claims not reiterated in the Office Action below is considered withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-14, 18, 19, 24-49, 51 and 52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14, 18, 19, 24-49, 51 and 52 are indefinite for reciting the phrase “*arbitrary* base sequence” because one of ordinary skill in the art could not reasonably determine the meets and bounds of this phrase. This phrase is not a term of the art, not is it clear from the specification what makes one nucleic acid sequence arbitrary from one that is not considered arbitrary.

Claim 11 is indefinite for reciting the phrases “immunological substances” and “receptor binding substances” because one of ordinary skill in the art could not reasonably determine the metes and bounds of a “substance”.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the introduction of new matter. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification does not adequately support the broad limitation "resin", only certain resin species (see paragraph 0311 of the specification).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14, 18, 19, 24-49, 51 and 52, are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hu, U.S. Patent Application Publication No. 2002/0048823, published on April 25, 2002, in view of Li, U.S. Patent Application Publication No. 2004/0018495 A1; and Wilding *et al.*, U.S. Patent No. 5,637,469, issued on June 10, 1997.

The independent claims, claims 1-10, 18-27, 51 and 52, are directed to an analytical device comprising, its method of making, and its method of use, wherein the device has:

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a first member having a groove, of specified width and depth, and a second member capable of covering the groove, wherein the groove forms a portion of a passage upon joining the first member and second member together and one of the first member and second member or both have a passage inlet and a passage outlet,

immobilizing a plurality of first nucleic acid species ($N1g$: g being an integer) each having an arbitrary base sequence at independent sites forming a zone within the passage for capturing one or more antigen species to be assayed,

then joining the first member and second member together by thermal fusion or with an adhesive to give an assembly with the passage formed therein,

introducing into the passage a reagent A containing conjugate species ($N2h-Lli$: wherein h and i are each an integer), each composed of one of a plurality of second nucleic acid species ($N2h$: h being an integer), each second nucleic acid species having a base sequence at least complementary to the base sequence of a corresponding species of the plurality of first nucleic acid species ($N1g$: g being an integer) immobilized in the capturing zone, and one of a plurality of antibodies as first ligand species (Lli : i being an integer), each first ligand species being capable of specifically binding to a corresponding species of the one or more antigen biological substance species to be assayed, and

allowing the plurality of conjugate species $N2h-Lli$ to specifically bind, for immobilization thereof, to the plurality of first nucleic acid species previously immobilized in the capturing zone.

Hu is directed towards compositions, methods and systems that comprise or use an array of a library of monoclonal antibodies for identifying a monoclonal antibody specific for a target antigen; or for profiling a plurality of unknown antigens from a particular source such as cells, cell lysates, tissues, or animals by the antigens' monoclonal antibody binding characteristics. Hu discloses that it is useful to find a monoclonal antibody for an antigen, or to characterize antigen from a particular source (e.g. a source comprising an animal having a disease) in order to develop tools for understanding a condition (e.g. the disease) in that source. Hu also teach conjugating the antibodies to nucleic acids and arraying the conjugated product:

“To create monoclonal antibody arrays, monoclonal antibodies or binding fragments of monoclonal antibodies are spotted, placed or affixed onto a

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substrate in a two-dimensional matrix or array. Preferably the substrate is "sticky" for the antibody (e.g. coated with biotin and capable of binding avidin covalently linked to the antibodies). The sample antigens, orphan or otherwise, (which contact the antibody array) can be tagged or labeled for detecting the bound antigen on the array. The orphan antigen or other target antigen can be tagged or labeled using radioactive labels, fluorophors, etc. Techniques for constructing arrays for polynucleotides are instructive to constructing arrays for monoclonal antibodies, including detecting the bound target antigens on the array after contact with the monoclonal antibodies."

Hu, paragraph 0019.

As in claim 14, Hu teaches fluorescent species for the label (paragraph 0019).

Although Hu teaches immobilizing the antibodies to the array such as through biotin/avidin, and acknowledges oligonucleotide arrays, he does not explicitly teach the immobilization to the substrate via an oligonucleotide, nor does Hu specifically teach the channel array hold the binding members.

Li is directed towards devices (as well as kits) and methods for assay that utilize antibody detection agents linked to solid substrates using an oligonucleotide linker (see Figures 3A, 4A, 4B, 6, and corresponding descriptions thereof). As in claims 12 and 13, Li teaches that the antibodies can either be the same or different for binding the antigen (see Figures and descriptions thereof). As in claims 27-49, which are directed to various arrangements of mixing, Li teaches that the conjugates may be formed in different orders (paragraphs 0009, 0013).

Wilding is directed towards devices methods of making and using the device for detecting the presence of a preselected analyte in a fluid sample. The devices comprise a substrate microfabricated to define a sample inlet port, and a mesoscale flow system that includes a sample flow channel extending from the inlet port. The mesoscale flow system further includes an analyte detection region in fluid communication with the flow channel comprised of a binding moiety for specifically binding the analyte. The detection region is constructed with a mesoscale dimension sufficiently small to enhance binding of the binding moiety and the analyte. The binding moiety may be immobilized in the detection region. The mesoscale detection systems of the invention may be used in a wide range of applications,

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including the detection of cells or macromolecules, or for monitoring reactions or cell culture growth. Wilding states:

“Capillary agglutination of red blood cells and immobilized anti-A antiserum was examined in a series of silicon substrates 14 (shown schematically in FIG. 6), fabricated with flow channels 20 of varying width. The silicon substrates 1-5 included flow channels 20A and B with a depth of 10 μm and widths ranging from 20 to 300 μm (Table 2). The inside surface of the channels were coated with anti-A (1:10 dilution) by first filling the channel with the antibody (capillary action) and allowing it to dry. A Type blood (diluted 1:5) was then introduced into channel 20 from inlet port 16 by capillary action and the channel was observed visually using a microscope (Leitz Aristomet).”

Wilding, paragraph 37 in the detailed description. Wilding also teaches the use of polymers (*i.e.*, resins – see col. 7, lines 15-37). Wilding also teaches that the device may be used to mix the added reagents as they are transported through certain channels.

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because each of Hu, Li and Wilding are directed towards the use of antibody based assays. One of ordinary skill in the art would have recognized the use of the oligonucleotide linking scheme of Li, including all the antibody reagents, such as the multiple antibodies, the ligands they bind to, and the individual oligonucleotide linkers between the antibody and the substrate, with the antibody array of Hu because of the ease at which the antibodies can be attached and can be positioned and identified on the array by sequence pairing.

One of ordinary skill in the art would have also been motivated to utilize the device of Wilding with the assay format of Hu because of the advantages the microfluidic capabilities and sample process that Wilding demonstrates. Furthermore, the various ways in which the reagents can be added and mixed are obvious given the direction of each of Li and Wilding. Therefore, the invention as a whole was *prima facie* obvious at the time it was invented.

Common Ownership of Claimed Invention Presumed

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. §§ 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Conclusions

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipso verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Jeffrey S. Lundgren/

Primary Examiner, Art Unit 1639